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Sun Pharma USA,
Caraco Pharmaceutical Laboratories, Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff v. SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL INC., SUN PHARMA GLOBAL FZE, SUN PHARMA USA, SUN PHARMACEUTICALS INDUSTRIES, INC. and CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	)	Civil Action No.: 14-cv-4307-JBS-KMW

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS
OF THE SUN DEFENDANTS TO FIRST AMENDED COMPLAINT

Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., Sun Pharma USA, and Caraco Pharmaceutical Laboratories, Ltd. (collectively, "Sun Defendants" or "Defendants"), by their attorneys, answer the First Amended Complaint ("Complaint") of Plaintiff Otsuka

Pharmaceutical Co., Ltd. ("Otsuka" or "Plaintiff") as follows, wherein paragraph numbers 1-51 correspond to those in the Complaint. Defendants deny all of the allegations of the Complaint not expressly admitted below.

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

Answer to Paragraph 1

Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1 and therefore deny the same.

2. Upon information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri - Kurla Road, Andheri (E), Mumbai, 400 059, India.

Answer to Paragraph 2

Admitted.

3. Upon information and belief, Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Upon information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Ltd.

Answer to Paragraph 3

Admitted.

4. Upon information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc.

Answer to Paragraph 4

Admitted.

5. Upon information and belief, Sun USA is a wholly-owned subsidiary of Sun Ltd., with its principal place of business at 1150 Elijah McCoy Drive, Detroit, MI, 48202.

Answer to Paragraph 5

Paragraph 5 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 5. Defendants state that Sun Pharma USA does not exist.

6. Upon information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Sun Pharmaceutical Industries, Inc. is the U.S. entity of Sun Ltd. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is an authorized agent of Sun Pharma Global FZE.

Answer to Paragraph 6

Paragraph 6 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Ltd., directly or indirectly through Sun Pharma Global Inc., and is a Michigan corporation, having a facility at 270 Prospect Plains Road, Cranbury, NJ 08512. Defendants deny the remaining allegations in Paragraph 6.

7. Upon information and belief, Caraco is a corporation organized and existing under the laws of Michigan, having a facility at 270 Prospect Plains Rd., Cranbury, NJ 08512. Upon information and belief, Caraco is a wholly-owned subsidiary of Sun Ltd. Upon information and belief, Caraco is an authorized agent of Sun Pharma Global FZE. Upon information and belief, Caraco may also be doing business as Sun Pharmaceutical Industries, Inc.

Answer to Paragraph 7

Paragraph 7 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 7. Defendants state that Caraco does not exist.

NATURE OF THE ACTION

8. This is an action for infringement of U.S. Patent No. 8,017,615 ("the '615 patent"), U.S. Patent No. 8,580,796 ("the '796 patent") and U.S. Patent No. 8,642,760 ("the '760 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Sun Pharma Global FZE's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell and offer to sell generic pharmaceutical products ("Sun Pharma Global FZE's generic products") before the expiration of the asserted patents.

Answer to Paragraph 8

Paragraph 8 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that Otsuka's Complaint purports to state a claim for infringement of U.S. Patent Nos. 8,017,615 ("the '615 patent"), 8,580,796 ("the '796 patent"), and 8,642,760 ("the '760 patent") relating to the filing of an ANDA for approval to market a generic product ("Sun's ANDA Product"). Defendants deny the remaining allegations in Paragraph 8.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

Answer to Paragraph 9

Paragraph 9 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that this Court has subject matter jurisdiction over Otsuka's claims asserted under 35 U.S.C. § 271(e)(2)(A), and denies the remaining allegations of Paragraph 9.

10. Upon information and belief, this Court has jurisdiction over Sun Ltd. Sun Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Ltd., directly or through its wholly-owned subsidiaries, including Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA, Sun Pharmaceutical Industries, Inc., and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Ltd. has

previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 10

Paragraph 10 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Ltd. in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 10.

11. Upon information and belief, this Court has jurisdiction over Sun Pharma Global Inc. Upon information and belief, Sun Pharma Global Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global FZE, Sun USA, Sun Pharmaceutical Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Sun Pharma Global Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 11

Paragraph 11 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharma Global Inc. in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 11.

12. Upon information and belief, this Court has jurisdiction over Sun Pharma Global FZE. Sun Pharma Global FZE is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharma Global FZE, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceutical Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sun Pharma Global FZE purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun USA, Sun Pharmaceuticals Industries, Inc. and Caraco, in this judicial district and this judicial district is a likely destination of Sun Pharma Global FZE's generic products. Sun Pharma Global FZE's authorized agent in this judicial district is John L. Dauer Jr., Esq., Chief Patent Counsel, Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512. Additionally, Sun Pharma Global FZE has availed itself of the laws of New Jersey by, at least, indicating that an

offer to access confidential information relating to Sun Pharma Global FZE's ANDA No. 78-614 "shall be governed by the laws of the State of New Jersey." Upon information and belief, Sun Pharma Global FZE has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 12

Paragraph 12 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharma Global FZE in this Court solely for purposes of this action, and deny the remaining allegations in Paragraph 12.

13. Upon information and belief, this Court has jurisdiction over Sun USA. Sun USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun USA, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun Pharmaceuticals Industries, Inc. and Caraco, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco's website states:

> Sun Pharma USA is the US arm of Sun Pharmaceutical Industries, Ltd. ("Sun Pharma"), a leading pharmaceutical company in India. Sun Pharma USA consists of Sun Pharma subsidiaries Caraco Pharmaceutical Laboratories, Ltd. with locations in the Detroit, MI area, New Jersey and Ohio . . . .

See http://www.caraco.com/aspx/CorporateProfile.aspx (emphasis added) (accessed June 4, 2014).

Answer to Paragraph 13

Paragraph 13 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 13. Defendants state that Sun Pharma USA does not exist.

14. Upon information and belief, this Court has jurisdiction over Sun Pharmaceuticals Industries, Inc. Sun Pharmaceuticals Industries, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sun Pharmaceutical Industries, Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, Sun USA, and Caraco, manufactures, markets, imports and sells generic drugs

throughout the United States and in this judicial district. Upon information and belief, Caraco's website states that Sun Pharmaceuticals Industries, Inc. "markets and distributes generic pharmaceuticals to the nation's largest wholesalers" and that it "is a vertically integrated manufacturer with the flexibility to develop and manufacture both in the U.S. and overseas." *See* http://www.caraco.com/aspx/CorporateProfile.aspx (accessed Sept. 29, 2014). In addition, Sun Pharmaceutical Industries, Inc. maintains "a focus on creating value with quality generic pharmaceuticals with strategic focus on the needs of U.S. health care system." *Id.* Sun Pharmaceuticals Industries, Inc. is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Sun Pharmaceuticals Industries, Inc. is registered in the State of New Jersey as a drug manufacturer and wholesaler, with Registration No. 5003437. Upon information and belief, Sun Pharmaceuticals Industries Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 14

Paragraph 14 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction with respect to Sun Pharmaceutical Industries Inc. solely for purposes of this action, and deny the remaining allegations in Paragraph 14.

15. Upon information and belief, this Court has jurisdiction over Caraco. Caraco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Caraco, directly or through its parent, subsidiaries, affiliates and/or agents, including Sun Ltd., Sun Pharma Global, Inc., Sun Pharma Global FZE, Sun USA, and Sun Pharmaceuticals Industries, Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Caraco is an authorized agent for Sun Pharma Global FZE in connection with ANDA No. 78-614. Upon information and belief, Caraco has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Answer to Paragraph 15

Paragraph 15 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants deny the allegations in Paragraph 15. Defendants state that Caraco does not exist.

16. Upon information and belief, the Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

Answer to Paragraph 16

Paragraph 16 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction in this Court with respect to Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc., solely for purposes of this action, and deny the remaining allegations in Paragraph 16.

17. Upon information and belief, the Defendants work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

Answer to Paragraph 17

Paragraph 17 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to personal jurisdiction in this Court with respect to Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc., solely for purposes of this action, and deny the remaining allegations in Paragraph 17.

18. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

Answer to Paragraph 18

Paragraph 18 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit to proper venue in this judicial district with respect to Sun Ltd., Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc., solely for purposes of this action, and deny the remaining allegations in Paragraph 18.

FIRST COUNT FOR PATENT INFRINGEMENT

19. The U.S. Patent and Trademark Office ("PTO") issued the '615 patent on September 13, 2011, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '615 patent is attached as Exhibit A.

Answer to Paragraph 19

Paragraph 19 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '615 patent bears the title "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof" and states that it was issued September 13, 2011, and that Exhibit A to the Complaint purports to be a copy of the '615 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 19 and therefore deny the same.

20. Otsuka is the owner of the '615 patent by virtue of assignment.

Answer to Paragraph 20

Paragraph 20 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '615 patent identifies Otsuka as the assignee. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 20 and therefore deny the same.

21. The '615 patent expires on December 16, 2024 (including pediatric exclusivity).

Answer to Paragraph 21

Paragraph 21 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book states that the '615 patent expires on December 16, 2024 (including pediatric exclusivity). Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 21 and therefore deny the same.

22. The '615 patent is directed to and claims, *inter alia*, pharmaceutical solid oral preparations and processes for preparing pharmaceutical solid oral preparations.

Answer to Paragraph 22

Paragraph 22 asserts legal conclusions for which no answer is required.

23. Otsuka is the holder of New Drug Application ("NDA") No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

Answer to Paragraph 23

Paragraph 23 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book lists Otsuka as the applicant for NDA No. 21-436 for aripiprazole tablets. Defendants deny the remaining allegations in Paragraph 23.

24. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

Answer to Paragraph 24

Paragraph 24 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book currently lists the '615 patent for NDA No. 21-436. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 24 and therefore deny the same.

25. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

Answer to Paragraph 25

Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 25 and therefore deny the same.

26. Upon information and belief, Sun Pharma Global FZE submitted ANDA No. 78-614 to the FDA, under Section 505(j), seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products in the United States.

Answer to Paragraph 26

Defendants admit that ANDA No. 78-614 was submitted to the FDA under 21 U.S.C. § 355(j), seeking approval to manufacture, use, sell, offer to sell, and import aripiprazole tablets in the United States, and that Sun Pharmaceutical Industries, Ltd. is the named applicant thereon. Defendants deny the remaining allegations in Paragraph 26.

27. Otsuka received a letter from Sun Pharma Global FZE's authorized agent, Caraco, dated May 23, 2014, ("Sun Pharma Global FZE's Letter") purporting to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '615 patent.

Answer to Paragraph 27

Paragraph 27 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that a Notice of Certification for ANDA No. 78-614 dated May 23, 2014, was served on Otsuka on behalf of Sun Pharma Global FZE by its authorized agent (*i.e.*, John L. Dauer, Jr., Esq., Chief Patent Counsel of an entity then known as Caraco Pharmaceutical Laboratories, Ltd.), under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '615 patent, and that Otsuka has admitted receipt of that letter. Defendants deny the remaining allegations of Paragraph 27.

28. Sun Pharma Global FZE's Letter states that "the established name of the proposed drug product that is the subject of the SUN ANDA is Aripiprazole Tablets."

Answer to Paragraph 28

Paragraph 28 asserts legal conclusions for which no answer is required. To the extent an answer may be required, admitted.

29. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

Answer to Paragraph 29

Denied.

30. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '615 patent.

Answer to Paragraph 30

Denied.

31. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

Answer to Paragraph 31

Denied.

SECOND COUNT FOR PATENT INFRINGEMENT

32. Otsuka realleges, and incorporates in full herein, paragraphs 23-28.

Answer to Paragraph 32

Defendants repeat, reallege, and incorporate by reference their responses to Paragraphs 23-28 of the Complaint as if fully set forth herein.

33. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

Answer to Paragraph 33

Paragraph 33 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '796 patent bears the title "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof" and states that it was issued November 12, 2013, and that Exhibit B to the Complaint purports to be a copy of the '796 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 33 and therefore deny the same.

34. Otsuka is the owner of the '796 patent by virtue of assignment.

Answer to Paragraph 34

Paragraph 34 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '796 patent identifies Otsuka as the assignee. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 34 and therefore deny the same.

35. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

Answer to Paragraph 35

Paragraph 35 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book states that the '796 patent expires on March 25, 2023 (including pediatric exclusivity). Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 35 and therefore deny the same.

36. The '796 patent is directed to and claims, *inter alia,* aripiprazole crystals.

Answer to Paragraph 36

Paragraph 36 asserts legal conclusions for which no answer is required.

37. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

Answer to Paragraph 37

Paragraph 37 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book currently lists the '796 patent for NDA No. 21-436. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 37 and therefore deny the same.

38. Sun Pharma Global FZE's Letter purports to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

Answer to Paragraph 38

Paragraph 38 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that a Notice of Certification for ANDA No. 78-614 dated May 23, 2014, was served on Otsuka on behalf of Sun Pharma Global FZE under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 38 and therefore deny the same.

39. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

Answer to Paragraph 39

Denied.

40. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '796 patent.

Answer to Paragraph 40

Denied.

41. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

Answer to Paragraph 41

Denied.

THIRD COUNT FOR PATENT INFRINGEMENT

42. Otsuka realleges, and incorporates in full herein, paragraphs 23-28.

Answer to Paragraph 42

Defendants repeat, reallege, and incorporate by reference their responses to Paragraphs 23-28 of the Complaint as if fully set forth herein.

43. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

Answer to Paragraph 43

Paragraph 43 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '760 patent bears the title "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof" and states that it was issued February 4, 2014, and that Exhibit C to the Complaint purports to be a copy of the '760 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 43 and therefore deny the same.

44. Otsuka is the owner of the '760 patent by virtue of assignment.

Answer to Paragraph 44

Paragraph 44 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the face of the '760 patent identifies Otsuka as the assignee. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 44 and therefore deny the same.

45. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

Answer to Paragraph 45

Paragraph 45 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book states that the '760 patent expires on March 25, 2023 (including pediatric exclusivity). Defendants are without knowledge

or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 45 and therefore deny the same.

46. The '760 patent is directed to and claims, *inter alia,* aripiprazole drug substance.

Answer to Paragraph 46

Paragraph 46 asserts legal conclusions for which no answer is required.

47. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

Answer to Paragraph 47

Paragraph 47 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that the FDA's Orange Book currently lists the '760 patent for NDA No. 21-436. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 47 and therefore deny the same.

48. Sun Pharma Global FZE's Letter purports to include a Notice of Certification for ANDA No. 78-614 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

Answer to Paragraph 48

Paragraph 48 asserts legal conclusions for which no answer is required. To the extent an answer may be required, Defendants admit that a Notice of Certification for ANDA No. 78-614 dated May 23, 2014 was served on Otsuka on behalf of Sun Pharma Global FZE under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 48 and therefore deny the same.

49. Upon information and belief, Sun Pharma Global FZE's generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

Answer to Paragraph 49

Denied.

50. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sun Pharma Global FZE has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-614 seeking approval to manufacture, use, sell and offer to sell Sun Pharma Global FZE's generic products before the expiration date of the '760 patent.

Answer to Paragraph 50

Denied.

51. Upon information and belief, Sun Pharma Global FZE's actions relating to ANDA No. 78-614 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of the Defendants.

Answer to Paragraph 51

Denied.

DEFENDANTS' ANSWER TO REQUEST FOR RELIEF

Defendants deny that Otsuka is entitled to the judgment or any other relief requested in Paragraphs 1 to 14 of Otsuka's request for relief in the "Wherefore" clause of the Complaint.

DEFENDANTS' AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth above, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Otsuka, Defendants assert the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(NON-INFRINGEMENT)

52. The manufacture, use, sale, offer for sale, and/or importation of the product that is the subject of Defendants' ANDA No. 78-614 does not infringe and will not infringe, directly or indirectly, any valid and enforceable claim of the '615, '796, and/or '760 patents, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY)

53. Each and every claim of the '615, '796, and '760 patents is invalid under 35 U.S.C. § 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, for obviousness-type double patenting, and/or other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

54. Otsuka's Complaint, in whole or in part, fails to state a claim upon which relief can be granted including, *inter alia*, any claims against Defendants Sun Pharma USA and Caraco Pharmaceutical Laboratories, Ltd. and any claims for exceptional case under 35 U.S.C. §§ 285 and/or 271(e)(4).

FOURTH AFFIRMATIVE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

55. This Court lacks subject matter jurisdiction to the extent Otsuka's claims of infringement are not limited to patent claims that cover only the product which is the subject of Otsuka's NDA No. 21-436 or methods of use such said product.

FIFTH AFFIRMATIVE DEFENSE
(NO COSTS UNDER 35 U.S.C. § 288)

56. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any of their costs in this action.

DEFENDANTS' COUNTERCLAIMS

Counterclaim Plaintiffs Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. (collectively

"Counterclaim Plaintiffs") for their counterclaims against Otsuka Pharmaceutical Co., Ltd. ("Otsuka" or "Counterclaim Defendant") allege and aver as follows:

THE PARTIES

1. Counterclaim Plaintiff Sun Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri - Kurla Road, Andheri (E), Mumbai, 400 059, India.

2. Counterclaim Plaintiff Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands, with a mailing address at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands.

3. Counterclaim Plaintiff Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), Sharjah, United Arab Emirates.

4. Counterclaim Plaintiff Sun Pharmaceutical Industries, Inc. is a Michigan corporation, having a facility at 270 Prospect Plains Road, Cranbury, NJ 08512.

5. Upon information and belief, Counterclaim Defendant Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

6. Upon information and belief, Otsuka is engaged in the research, development, manufacture, and sale of pharmaceutical products.

JURISDICTION AND VENUE

7. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has personal jurisdiction over Otsuka because Otsuka has availed itself of the rights and privileges of this forum, and subjected itself to the jurisdiction of this forum, by suing Counterclaim Plaintiffs in this District, and/or because, upon information and belief, Otsuka conducts continuous and substantial business in this District.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

11. Upon information and belief, U.S. Patent No. 8,017,615 ("the '615 patent"), entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof," was issued on September 13, 2011.

12. Upon information and belief, U.S. Patent No. 8,580,796 ("the '796 patent"), entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof," was issued on November 12, 2013.

13. Upon information and belief, U.S. Patent No. 8,642,760 ("the '760 patent"), entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." was issued on February 4, 2014.

14. The '615, '796, and '760 patents are listed in the FDA's Electronic Orange Book for aripiprazole tablets (Abilify®).

15. Otsuka claims to have the right to enforce the '615, '796, and '760 patents.

16. Otsuka claims to be the current holder of New Drug Application ("NDA") No. 21-436 (the "Abilify® NDA") for aripiprazole tablets (Abilify®).

17. Abbreviated New Drug Application No. 78-614 ("ANDA No. 78-614" or "Sun's ANDA") was submitted to the FDA under 21 U.S.C. § 355(j) on behalf of one or more

Counterclaim Plaintiffs, to obtain FDA approval for an aripiprazole tablet product ("Sun's ANDA Product") for the activities stated in Sun's ANDA.

18. Counterclaim Plaintiffs included in Sun's ANDA, in good faith and with an objective, reasonable basis, paragraph IV certifications for the '615, '796, and '760 patents.

THE ACTUAL CONTROVERSY

19. Otsuka filed a Complaint and a First Amended Complaint against Counterclaim Plaintiffs in this District alleging infringement of the '615, '796, and '760 patents.

20. An actual, substantial, and continuing justiciable case or controversy exists between Counterclaim Plaintiffs and Otsuka regarding the non-infringement, invalidity, and/or unenforceability of the '615, '796, and '760 patents.

FIRST COUNTERCLAIM
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT)

21. Counterclaim Plaintiffs repeat, reallege, and incorporate by reference the allegations of paragraphs 1-20 of these Counterclaims as if fully set forth herein.

22. This counterclaim is for a declaration that Counterclaim Plaintiffs have not infringed, directly or indirectly, and do not and will not infringe, directly or indirectly, any valid and enforceable claim of the '615, '796, and/or '760 patents, either literally or under the doctrine of equivalents.

23. This counterclaim is for a declaration that the manufacture, use, sale, and offer for sale in the United States, and importation into the United States, of Sun's ANDA Product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '615, '796, and/or '760 patents, either literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM
(DECLARATORY JUDGMENT OF INVALIDITY

24. Counterclaim Plaintiffs repeat, reallege, and incorporate by reference the allegations of paragraphs 1-23 of these Counterclaims as if fully set forth herein.

25. This counterclaim is for a declaration that each and every claim of the '615, '796, and '760 patents is invalid under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, for obviousness-type double patenting, and/or other judicially-created bases for invalidation.

DEFENDANTS'/COUNTERCLAIM PLAINTIFFS' REQUEST FOR RELIEF

Wherefore, Counterclaim Plaintiffs Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharma Global Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. ("Counterclaim Plaintiffs"; and together with Sun Pharma USA and Caraco Pharmaceutical Laboratories, Ltd., "Defendants") respectfully requests that:

(a) Judgment be entered in favor of Defendants on Otsuka's Complaint, that the Complaint against Defendants be dismissed with prejudice, and that Otsuka take nothing thereby;

(b) Judgment be entered that the manufacture, use, offer to sell, or sale in the United States, or importation into the United States, of the product that is the subject of Sun's ANDA No. 78-614 does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '615, '796, and '760 patents, either literally or under the doctrine of equivalents;

(c) Judgment be entered that Defendants have not infringed, directly or indirectly, any valid and enforceable claim of the '615, '796, and '760 patents, either literally or under the doctrine of equivalents;

(d) Judgment be entered that each and every claim of the '615, '796, and '760 patents is invalid;

(e) The Court permanently enjoin Otsuka and its assigns, successors, officers, agents, servants, employees, attorneys, licensees, and any person who acts in concert or participation with any of them, from asserting that the manufacture, use, offer to sell, or sale in the United States, or importation into the United States, of the product that is the subject of ANDA No. 78-614 has infringed, infringes, or will infringe, any claim of the '615, '796, and '760 patents, directly or indirectly, either literally or under the doctrine of equivalents;

(f) This case be deemed an exceptional case with Defendants as the prevailing party under 35 U.S.C. § 285;

(g) The Court award Defendants their attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

(h) The Court award Defendants their costs; and

(i) The Court award Defendants such other and further relief as is just and proper.

Dated: November 19, 2014

Respectfully submitted,

s/ Gregory D. Miller

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